PATENT
Attorney Docket No. **HOGAN-06650**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :	Kirk Hogan	
Serial No.:	09/976,423	Group No.: 1634
Filed:	10/21/2001	Examiner: J.A. Goldberg
Entitled:	Methods and Compositions for Perioperative Genomic Profiling	

DECLARATION OF MORRIS WAXLER, Ph.D. UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)(1)(i)(B)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being sent by facsimile transmission to the U.S. Patent and Trademark Office, via Examiner J.E. Goldberg at (703) 746-5149.

Dated: 9-8-03 By: Mary Ellen Waite
Mary Ellen Waite

Madam:

1. I, Morris Waxler, am a specialist in Food & Drug Administration regulatory affairs at the law firm of LaFollette, Godfrey & Kahn.

2. As a Branch Chief at the Center for Devices and Radiological Health of the Food & Drug Administration for 26 years, I am knowledgeable about Food & Drug Administration requirements for the manufacture and marketing of approved medical devices and diagnostic kits.

3. Instructions for the use of an *in vitro* genetic diagnostic kit bear a critical functional relationship to other components of the kit.

4. The function of an *in vitro* genetic diagnostic kit depends on the instructions to be approved by the Food &Drug Administration; without instructions the *in vitro* genetic diagnostic kit is not considered to be functional by the Food & Drug Administration.

5. Therefore an *in vitro* genetic diagnostic kit does not, and cannot, function equally effectively with or without instructions.

6. The functional relationship between an *in vitro* genetic diagnostic kit and its operation is critical such that component instructions must undergo rigorous Food & Drug Administration scrutiny before the kit may be manufactured or marketed in order to assure its safety, efficacy and reliability.

7. Without Food & Drug Administration approved instructions for its operation an *in vitro* genetic diagnostic kit cannot be manufactured or marketed.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: September 7, 2003 Signed: Morris Waxler
Morris Waxler, Ph.D.